**PATENT APPLICATION**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of

GILSON et al.

Appln. No.: 10/058,828

Confirmation No.: 3776

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For: EMBOLIC PROTECTION DEVICE

Docket No: A8937

Group Art Unit: 3731

Examiner: Uyen T. Ho

## DECLARATION OF MAIRSIL CLAFFEY

**MAIL STOP AMENDMENT**
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I Mairsil Claffey, do declare and state as follows:

1. I am a citizen of the Republic of Ireland, and reside at 94 Costa na Mara, Oranmore, Co. Galway.
2. This declaration is submitted in support of a request for interference with U.S. Patent Application Serial No. 09/723,003, filed November 27, 2000, pursuant to 37 C.F.R. §41.202(a).
3. From May 1997 to 2001, I was the Quality Assurance and Regulatory Manager of MedNova (referred to herein as "MedNova").
4. During MedNova's development and design of embolic filter protection systems, I worked closely with Paul Gilson, Eamon Brady, Padraig Maher, David Vale, and Chas Taylor (referred to herein collectively as "the inventors"), and regularly participated in meetings and conferences

concerning the design of the embolic filter system. I am familiar with their work and with the work of other MedNova researchers and engineers in developing this product.

## I. BACKGROUND

5. At the time of the events described herein, MedNova was a small start-up company located in Galway, Ireland.
6. During the events described herein, Paul Gilson was employed by MedNova as Executive Director and Chief Scientific Officer. During this period, Paul Gilson was responsible for Operations, Research and Development, Regulatory Affairs and Quality Control.
7. During the events described herein, Eamon Brady was engaged by MedNova as Research and Development Manager. During this period, Eamon Brady was responsible for MedNova's embolic filter protection device development project.
8. During the events described herein, Padraig Maher was employed by MedNova as a Research and Development Engineer.
9. During the events described herein, David Vale was employed by MedNova as a Senior Research and Development Engineer.
10. During the events described herein, Chas Taylor was employed by MedNova as Executive Director and Marketing Director. During this period, Chas Taylor's responsibilities at MedNova included clinical studies, marketing and sales.
11. During the events described herein, John O'Shaughnessy was employed by MedNova as Executive Director and CEO of MedNova, and participated in meetings and conferences with the inventors and other employees

concerning the design of the embolic filter system, and their responsibilities in its development.

12. At the time of the events described herein, MedNova's research and development activities were directed to two potential product lines, one of which was an embolic protection device. The embolic protection system was MedNova's principal research and development project during the time of the events described herein.

13. Because MedNova was a small company, concentrating principally on development of embolic protection systems and methods for using them, I and other employees working on the embolic filter project worked closely with the inventors, on a daily basis, and were familiar with their basic concept and with the refinements and developments of the filter which led to the filing of Irish Patent Application 98 0267 on April 8, 1998.

14. Because I had primary responsibility for quality assurance and regulatory approval of the embolic filter protection system, I was familiar with the design and development of the embolic protection filter device, including the system for introducing, deploying, and removing the filter device from a vessel, and the methods for using the system contemplated by the inventors, from its inception and throughout its development. I prepared various submissions for regulatory approval of the filter system in Europe, which described in detail the various components of the system and methods for their use invented by the inventors.

15. In order to demonstrate that an embolic protection device is practically useful, and that it may be used safely and effectively, it is essential to develop a number of components that are required to use the filter, including, for example: an embolic filter element, having appropriately

sized holes for filtering emboli from the blood while maintaining blood flow in the vessel, and a suitable material and configuration for the supporting frame and struts that will ensure deployment to engage a wall of the vessel; a suitable guidewire size and configuration, such that rotation or distal translation of the guide wire relative to the filter element does not displace the filter element; a delivery catheter for transluminally inserting the filter element into a vessel, which permits reliable deployment of the filter element so that the struts and filter sac expand to engage a wall of the vessel; and a retrieval catheter which permits the filter element containing emboli to be withdrawn from the vessel.

16. Because the device is intended to be used in interventional procedures including carotid artery angioplasty, it is also essential to ensure the structural integrity of each of these components during performance of such procedures; provide suitable methods for sterilizing each component; and determine dimensions such as the size of the filter sac holes which will capture emboli of concern, while maintaining sufficient blood flow, and the thickness of the filter sac which is required to provide structural integrity.

17. By February, 1998, MedNova's research and development activities were almost entirely directed to development of a practically useful embolic filter protection device suitable for use in carotid artery angioplasty procedures.

18. From February, 1998, until April 8, 1998, nine researchers employed by MedNova, including the inventors, were engaged in a continuous effort to produce a practically useful embolic protection device.

19. From February, 1998, until April 8, 1998, Paul Gilson and Chas Taylor were responsible for *ex vivo* evaluations of prototype embolic filter

protection devices and methods; Paul Gilson had responsibility for development of guidewires for use with the filter system; Eamon Brady had responsibility for the filter development project; Padraig Maher was wholly engaged as an R and D engineer with responsibilities including producing embolic protection devices; and David Vale was wholly responsible for the retrieval catheter used to retrieve the filter element from the artery after performance of carotid artery angioplasty procedures.

20. From February, 1998, until April 8, 1998, I worked closely with the inventors and with other employees of MedNova who were engaged in making and testing the components of the embolic protection filter system, and was aware of their activities on a daily basis.

21. The employees worked together in a team structure. There was crossover but described herein are the specific responsibilities of the various people involved. The employees working on the embolic filter protection device and method were Keith Ryan, a Research and Development Engineer who was generally responsible for PTFE shrink development work, which was necessary to make the delivery catheters used to transluminally insert the filter into a vessel; Shivaun O'Rourke, a Quality Assurance Engineer who had duties including test development and evaluation of prototype devices, including filter elements, delivery and retrieval catheters; Susan Eighan, a Manufacturing Engineer who was generally responsible for catheter manufacturing line setup, and for Nitinol forming and sac bond process development used in producing the embolic filter element; Mary Gallagher, Shivaun O'Rourke, Jon Hager and myself were members of the quality assurance team and regulatory team and had duties including vendor approval, receiving goods system, documentation and reviewing and

approving sterility procedures for producing the embolic protection device; and Steven Horan, a Research and Development Engineer had duties including filter sac ("balloon") development.

22. I have read and understand the two counts which are proposed for the interference that are described herein.

| **Proposed Count 1**<br>**(Gilson Claim 97)** |
|---|
| A method of filtering emboli from blood flowing through a vessel, the method comprising:<br><br>providing a guide wire<br><br>having a distal stop,<br><br>and a filter element having a capture ring disposed for translation on the guide wire proximal of the stop;<br>transluminally inserting the guide wire and filter element into a vessel;<br><br>deploying the filter element to engage a wall of the vessel, the filter element filtering emboli out of blood flowing through the vessel;<br><br>advancing a treatment device along the guide wire to treat a portion of the vessel proximal to the location of the filter element,<br><br>rotation or distal translation of the guide wire relative to the filter element not displacing the filter element. |

| **Proposed Count 2**<br>**(Gilson Claim 98)** |
|---|
| A method of filtering emboli from blood flowing through a vessel, the method comprising:<br><br>providing a guide wire having a distal region<br><br>including a distal stop,<br>and a filter element disposed for translation on the guide wire proximal to the distal stop,<br><br>the filter element comprising a plurality of self-expanding struts having a filter |

> sac affixed thereto;
>
> transluminally inserting the guide wire and filter element into a vessel;
>
> deploying the filter element so that the struts and filter sac expand to engage a wall of the vessel, the filter sac filtering emboli out of blood flowing through the vessel;
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> advancing a treatment device along the guide wire to treat a portion of the vessel proximal to the location of the filter element,
>
> rotation or distal translation of the guide wire relative to the filter element not displacing the filter element;
>
> further comprising retracting the guide wire in a proximal direction to cause the distal stop to abut against the filter element.

23. Subsequent to January 1, 1996, and prior to March 5, 1998, the inventors described to me each aspect of their invention defined by Count 1.
24. Subsequent to January 1, 1996, and prior to March 5, 1998, the inventors described to me each aspect of their invention defined by Count 2.
25. All events referred to herein occurred subsequent to January 1, 1996.
26. From a time prior to March 5, 1998, until the filing of Irish Patent Application No. 98 0267 on April 8, 1998, the inventors and other MedNova employees were engaged in continuous, diligent activity directed to achieving a reduction to practice of the invention defined by Count 1 in Ireland and in the United States.
27. From a time prior to March 5, 1998, until the filing of Irish Patent Application No. 98 0267 on April 8, 1998, the inventors and other MedNova employees, were engaged in continuous, diligent activity directed to achieving a reduction to practice of the invention defined by Count 2 in Ireland and in the United States.

28. Their activities relating to conception, diligence and reduction to practice of the inventions defined by Count 1 and Count 2 are described in more detail as follows.

## II. CONCEPTION

29. With respect to Count 1, prior to March 5, 1998, the inventors disclosed to me an embodiment of their invention that is disclosed in Irish Application No. 97 0789, filed on November 7, 1997, as described in the following table:

| **Disclosure of Irish Application No. 97 0789** |
|---|
| A filter element that provides a pathway for blood and has means for capturing and retaining undesired embolic material released during an interventional procedure (page 11, lines 19-24).<br><br>The device is used in an over the wire transcatheter configuration, in which the clinician will cross the lesion with a steerable guidewire (page 12, lines 3-5).<br><br>The device consists of a filter attached to a shaft that can run over the primary crossing guidewire (page 12, lines 11-13); the shaft is disposed for translation on the guide wire proximal of the distal end of the guidewire, for example, substrate shaft 33 in Figs. 11-15 and 18, which is threaded over a guidewire (page 16, lines 6-8).<br><br>The clinician will cross the lesion with a steerable guidewire, and the filter is then threaded over the guidewire and placed distal to the site of the lesion being treated (page 12, lines 4-8).<br><br>The filter is deployed into the vessel and will capture emboli (page 12, lines 8-11); the deployed filter element will occlude the vessel except for the path or paths provided through the filter (page 12, lines 21-24).<br><br>The deployed filter is placed distal to the site of the lesion being treated and will capture emboli that are generated or dislodged during balloon |

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| inflation and stent placement, which are treatment devices advanced along the guide wire to a position proximal to the location of the filter (page 12, lines 4-11; page 19, lines 10-17; Claims 23, 24).<br><br>Because the shaft or hollow support element (page 12, lines 14-18) on which the filter is mounted is not fixed to the guidewire (page 12, lines 11-13), rotation or distal translation of the guidewire relative to the filter element does not displace the filter element. The guidewire moves independently from the filter:<br>it is first steered across the lesion, and the filter is then threaded over the inserted guidewire and deployed in the vessel (page 12, lines 3-11). During retrieval, the filter can be withdrawn either with the guidewire or over it (page 16, lines 23-25). The filter is attached to a shaft that can run over the prior crossing guidewire (page 12, lines 11-13), and rotation or distal translation of the guidewire relative to the shaft thus does not displace the filter element. |

30. Prior to March 5, 1998, the inventors disclosed to me an embodiment of their invention that is disclosed in a drawing from David Vale's laboratory notebook which is attached as Exhibit 1. At the time that Exhibit 1 was made, I met frequently with the inventors to discuss the initial design of the embolic filter and system. For a period of time, I shared an office with Eamon Brady. The inventors disclosed to me, and I understood the filter protection system described in Exhibit 1 and the methods for its use during angioplasty and stenting procedures, prior to March 5, 1998. More particularly, I confirm that the inventors disclosed to me and I understood each of the following components and uses of the embolic filter protection system described in Exhibit 1, prior to March 5, 1998.

31. Exhibit 1 is an accurate description of an embodiment of an embolic protection system as drawn by David Vale and as that embodiment existed prior to March 5, 1998. The system was called the "Neuroguard" system, and Exhibit 1 illustrates the details and dimensions of a delivery catheter

having a Y-shaped Touhy Borst adapter and a catheter shaft of wound springwire having a Teflon® (*i.e.*, polytetrafluoroethylene or "PTFE") heat-shrink cover. The delivery catheter is used to transluminally insert a guidewire and a filter element into a blood vessel, and to deploy the filter element in the blood vessel.

32. The filter element is described as a "Chronoflex"™, (*i.e.*, polyurethane which is used to form a membrane) balloon filter sac mounted on a polyimide tube support.

33. The "Chronoflex"™ balloon filter is illustrated in an expanded configuration, in which a "balloon" filter having a thickness of 0.002″ is attached by adhesive to the polyimide tube and to a Nitinol framework which supports the filter sac.

34. The balloon or membrane filter is shown with large orifices at the proximal end of the filter, which permit the entry of blood containing emboli, and with smaller orifices at the distal end of the filter, which filter emboli from blood flowing through the filter and out the smaller orifices.

35. Nitinol is a self-expanding material, and in the illustrated embodiment the self-expanding filter sac is shown in its deployed configuration, expanded by a supporting Nitinol framework which has four struts attached to a proximal ring which is adjacent to the larger filter openings at the proximal end of the filter.

36. Within the inner lumen of the polyimide tube, which has a diameter of 0.0145″, is disposed a guidewire having a maximum shaft diameter of 0.014″ to allow for rotation and translation of the guidewire relative to the filter element.

37. I understood from the inventors at the time that Exhibit 1 was made, that the filter element is advanced along a guide wire, and that they considered it important that rotation or distal translation of the guide wire relative to the filter element would not displace the deployed filter element. I also understood at that time that in the system described in Exhibit 1, the guidewire may be rotated or distally translated relative to the polyimide tube without displacing the filter mounted on the tube, because the inner diameter of the polyimide tube is larger than the diameter of the guidewire.

38. In Exhibit 1, the guidewire extends through the inner lumen of the filter element polyimide tube, and extends beyond the distal end of the filter, which is disposed near the distal end of the guidewire.

39. Exhibit 1 also refers to an interface of the filter element polyimide tube and treatment devices including a balloon catheter and a stent balloon catheter, which are indicated to have a minimum lumen interior diameter of 0.020″.

40. As confirmed by Exhibit 1, the inventors disclosed to me that conventional treatment devices such as a balloon catheter and a stent balloon catheter may be advanced along the guidewire over the polyimide tube of the filter, which has an outer diameter of 0.0179″.

41. With regard to Count 1, prior to March 5, 1998, the inventors disclosed to me the following aspects of their invention which are shown in Exhibit 1:

| **Neurogard Details and Dims.** |
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| The CHRONOFLEX balloon filter is used in the method disclosed in Irish Application No. 97 0789, as shown, *e.g.*, in Fig. 18.<br><br>Guidewire having a maximum shaft outer diameter (O.D.) of 0.014″. The balloon filter is disposed on a polyimide tube having an inner diameter (I.D.) of 0.0145″, and is thus disposed for translation on the guide wire proximal of the distal end of the guide wire. |

> Exhibit 1 illustrates the filter polyimide tube support and guidewire extending from a delivery catheter that is transluminally inserted into a vessel, as described in Irish Application No. 97 0789.
>
> The self-expanding CHRONOFLEX filter is shown in deployed configuration, as described in Irish Application No. 97 0789, to engage a wall of the vessel and filter emboli out of blood flowing through a vessel in which the filter is deployed.
>
> Treatment devices such as a balloon catheter or a stent balloon catheter disclosed in Exhibit 1 are inserted into a vessel to treat a portion of the vessel, and are advanced along the guidewire to a position proximal of the filter element, as described in Irish Application No. 97 0789.
>
> Because Exhibit 1 describes the inner lumen of the polyimide tube as having a diameter of 0.0145″, and the guidewire has a maximum shaft outer diameter of 0.014″, Exhibit 1 discloses that rotation or distal translation of the guide wire relative to the filter element does not displace the filter element.

42. Prior to March 5, 1998, the inventors disclosed to me their concept of a dual-diameter or "stepped" guidewire with a distal end region having a diameter greater than the proximal diameter, which permits the filter element to translate distally and rotate on the guidewire proximal of the thicker distal end, but prevents translation of the filter distal to the thicker distal end.

43. I understood at that time that in the filter element shown in Exhibit 1, the polyimide tube on which the balloon filter is mounted is designed to rotate and translate on the guidewire, because the guidewire has a smaller diameter (0.014″) than the inner lumen of the polyimide tube (0.0145″).

44. On February 13, 1998, I sent an email message to Paul Gilson (Exhibit 100) identifying my schedule for returning from maternity leave. I indicated that I would work a half day either Thursday, February 19, 1998, or Friday,

February 20, 1998, followed by half days on Wednesday, February 25, 1998, through Friday, February 27, 1998, and then half days the week of Monday, March 2, 1998, through Friday, March 6, 1998. I reviewed all the documents addressed to me during my maternity leave while I was returning to the office on a part-time basis. While I was on maternity leave, Mary Gallagher took my place on a contract basis for two days per week.

45. Prior to March 5, 1998, the inventors disclosed to me that the small clearance between the guidewire and the polyimide tube caused undesirable friction between the guidewire and the tube.

46. In a conference call design review meeting prior to March 5, 1998, Chas Taylor proposed to solve this problem by using a custom guidewire, having a thinner proximal portion on which the filter element polyimide tube support is mounted. He suggested using a stepped guidewire having a proximal diameter of 0.012″ and a distal end diameter of 0.018″.

47. Prior to March 5, 1998, I received an email describing the conference call meeting which was attended by inventors Chas Taylor, Padraig Maher, David Vale and Eamon Brady, and also by John O'Shaughnessy, which is attached as Exhibit 3.

48. Prior to March 5, 1998, the inventors disclosed to me that a stepped guidewire, having a distal end portion with a diameter greater than the inner diameter of the polyimide tube (0.0145″) would serve as a distal stop, which limits distal translation of the filter on the guidewire.

49. Prior to March 5, 1998, the inventors disclosed to me that because of the stepped guidewire configuration, the guidewire cannot be removed proximally through the polyimide support of the filter element. It is

necessary to backload the stepped guidewire through the filter support in order to prepare the filter system for use.

50. Prior to March 5, 1998, the inventors disclosed to me that they considered that the optimal stepped guidewire configuration for use with a polyimide tube filter support having an inner diameter of 0.0145″ was a custom guidewire having a proximal diameter of 0.013″, which would permit rotation and distal translation of the filter on the proximal portion of the guidewire, and a distal end diameter of 0.016″, which would act as a distal stop.

51. Prior to March 5, 1998, MedNova used a custom 0.013″/0.016″ guidewire in prototype filter systems including the "Mark 1 NeuroShield" filter system described in Exhibit 90.

52. Prior to March 5, 1998, the inventors and other MedNova employees constructed an embodiment of a prototype filter device and system which was designated as the "NeuroShield Mark 1" embolic filter protection system. I am familiar with the construction of this prototype. A true and accurate photograph of the NeuroShield Mark 1 embolic filter protection system prototype is attached as Exhibit 90.

53. With regard to Count 1, prior to March 5, 1998, I understood that the prototype NeuroShield Mark 1 filter system included the following features of the invention:

| **NeuroShield Mark 1 Prototype (Exhibit 90)** |
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| The filter system is used in the method disclosed in Irish Application No. 97 0789, where a representative filter is shown, *e.g.*, in Fig. 18.<br><br>The balloon filter shown in Exhibit 90 is mounted on a polyimide tube support having an inner diameter of 0.0145″, and the filter is disposed |

for translation on the guide wire proximal of the distal stop of the guide wire. The polyimide tube support prevents the filter from translating distal of the guidewire stop.

Exhibit 90, shows the filter polyimide tube support and guidewire being inserted into a delivery catheter that is transluminally inserted into a vessel, as described in Irish Application No. 97 0789.

The balloon filter is shown in Exhibit 90, in its deployed configuration, as described in Irish Application No. 97 0789, to engage a wall of the vessel and filter emboli out of blood flowing through a vessel in which the filter is deployed.

Treatment devices such as a balloon catheter or a stent balloon catheter disclosed in Irish Application No. 97 0789 are inserted into a vessel to treat a portion of the vessel, and are advanced over the guidewire to a position proximal of the filter element, as described in Irish Application No. 97 0789.

The inner lumen of the polyimide tube filter support shown in Exhibit 90 has a diameter of 0.0145″, and the proximal region of the guidewire has an outer diameter of 0.013″. Exhibit 90 thus confirms that rotation or distal translation of the guide wire relative to the filter element would not displace the filter element. The guidewire can be translated through the filter polyimide tube support without displacing the filter element. The guidewire can also be rotated in the filter polyimide tube support without displacing the filter element.

The filter system shown in Exhibit 90 is used in the methods described in Irish Application 97 0789, in which the guidewire is first steered across the lesion, through the filter support, and the filter is then threaded over the inserted guidewire and deployed in the vessel (page 12, lines 3-11). The filter is attached to a shaft that can run over the prior crossing guidewire (page 12, lines 11-13), and rotation or distal translation of the guidewire relative to the filter support shaft thus does not displace the filter element.

54. Prior to March 5, 1998, I understood that the filter system shown in Exhibit 90 was designed by the inventors to be used in the methods described in Irish Application 97 0789, in which the guidewire is first steered across the lesion, through the filter support, and the filter in a collapsed configuration in a delivery catheter is then threaded over the inserted guidewire and deployed in the vessel. The filter is attached to a polyimide shaft that can run over the prior crossing guidewire, and rotation or distal translation of the guidewire relative to the filter support shaft does not displace the filter element. I understood that treatment devices such as a balloon catheter or a stent balloon catheter are inserted into a vessel to treat a portion of the vessel, and are advanced over the guidewire to a position proximal of the expanded filter element. I understood that one significant advantage of the filter system shown in Exhibit 90 was that that guidewire could be manipulated independently relative to the filter element, and could be extended through the filter element and rotated without displacing the filter element. The inventors disclosed to me that independent translation and rotation of the guidewire relative to the filter element would have significant advantages in steering the guidewire into position in a vessel, past a stenosis partially closing the vessel, prior to inserting and deploying the filter in the vessel.

55. With regard to Count 2, prior to March 5, 1998, the inventors disclosed to me the following aspects of their invention which are described in Irish Application No. 97 0789:

| **Disclosure of Irish Application No. 97 0789** |
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| A filter element provides a pathway for blood and has means for capturing and retaining undesired embolic material released during a |

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| surgical procedure (page 11, lines 19-24).<br><br>The device is used in an over the wire transcatheter configuration, in which the clinician will cross the lesion with a steerable guidewire (page 12, lines 3-5).<br><br>The device consists of a filter attached to a shaft that can run over the primary crossing guidewire (page 12, lines 11-13); the shaft is disposed for translation on the guide wire proximal of the distal end of the guidewire, for example, substrate shaft 33 in Figs. 11-15 and 18 which is threaded over a guidewire (page 16, lines 6-8).<br><br>Fig. 18 discloses a filter element having a plurality of Nitinol shape-memory struts, formed to remember an open shape, having a balloon filter affixed to the support (page 18, lines 9-14); the membrane filter fabric may be bonded to the supporting spoke framework (page 15, lines 25-31) or attached over the Nitinol frame (page 17, lines 6-7).<br><br>The clinician will cross the lesion with a steerable guidewire, and the filter is then threaded over the guidewire and placed distal to the site of the lesion being treated (page 12, lines 4-8).<br><br>The self-expanding filter of Fig. 18 is deployed in the vessel and will capture emboli (page 12, lines 8-11); the expanded filter element will occlude the vessel except for the path or paths provided through the filter (page 12, lines 21-24).<br><br>The deployed filter will capture emboli that are generated or dislodged during balloon inflation and stent placement, which are treatment devices advanced along the guide wire to a position proximal to the location of the filter (page 12, lines 8-11; page 19, lines 10-17; claims 23, 24).<br><br>Because the shaft or hollow support element (page 12, lines 14-18) on which the filter is mounted is not fixed to the guidewire (page 12, lines 11-13), rotation or distal translation of the guidewire relative to the filter element does not displace the filter element. The guidewire moves independently from the filter:<br>it is first steered across the lesion, and the filter is then threaded over the inserted guidewire and deployed in the vessel (page 12, lines 3-11). |

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| During retrieval, the filter can be withdrawn either with the guidewire or over it (page 16, lines 23-25). The filter is attached to a shaft that can run over the prior crossing guidewire (page 12, lines 11-13), and rotation or distal translation of the guidewire relative to the filter support shaft thus does not displace the filter element. |

56. With regard to Count 2, prior to March 5, 1998, the inventors disclosed to me the embodiment described in Exhibit 1, and I appreciated at that time that Exhibit 1 discloses the following aspects of their invention:

| **Neurogard Details and Dims.** |
|---|
| The CHRONOFLEX balloon filter is used in the method disclosed in Irish Application No. 97 0789, as shown in Fig. 18.<br><br>Guidewire having a maximum shaft outer diameter (O.D.) of 0.014″.<br><br>The balloon filter is disposed on a polyimide tube having an inner diameter (I.D.) of 0.0145″, and is thus disposed for translation on the guide wire proximal to the distal end of the guide wire.<br><br>Self-expanding Nitinol shape-memory struts support the filter sac, shown with large proximal holes and small distal holes, in expanded configuration.<br><br>Exhibit 1 illustrates the filter polyimide tube support and guidewire extending through a delivery catheter that is transluminally inserted into a vessel, as described in Irish Application No. 97 0789.<br><br>The self-expanding CHRONOFLEX filter is shown in deployed configuration, as described in Irish Application No. 97 0789, to engage a wall of the vessel and filter emboli out of blood flowing through a vessel in which the filter is deployed.<br><br>Treatment devices such as a balloon catheter or a stent balloon catheter are treatment devices which are inserted into a vessel to treat a portion of the vessel, and in the device shown in Exhibit 1, they are advanced along |

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| the guidewire to a position proximal of the filter element, as described in Irish Application No. 97 0789.<br><br>Because Exhibit 1 describes the inner lumen of the polyimide tube as having a diameter of 0.0145″, and the guidewire has a maximum shaft outer diameter of 0.014″, Exhibit 1 discloses that rotation or distal translation of the guide wire relative to the filter element does not displace the filter element. |

57. As stated above, prior to March 5, 1998, the inventors disclosed to me their conception of a stepped guidewire, having a distal stop which restricted distal translation of the filter element on the guidewire.

58. As shown in Exhibit 1, the polyimide tube on which the balloon filter is mounted was designed to rotate and translate on the guidewire, because the guidewire had a smaller diameter (0.014″) than the inner lumen of the polyimide tube (0.0145″).

59. Prior to March 5, 1998, the inventors disclosed to me that a small clearance between the guidewire and the polyimide tube caused undesirable friction between the guidewire and the tube.

60. Prior to March 5, 1998, I received an email from Padraig Maher on the subject “Review of Polyimide tubing functionality,” which was sent to Eamon Brady, Fergal Farrell, John O’Shaughnessy, Mairsil Claffey; Susan Eighan, Ruth Houlihan, and Paul Gilson, and is attached as Exhibit 2.

61. As Padraig Maher disclosed in Exhibit 2, the inventors informed me that that the lumen was too tight for the guidewire over the 3 meter length of the polyimide tube. The inventors also appreciated that it would be desirable to devise a mechanism for locking the polyimide tubing to the guide wire.

62. In the embodiment disclosed in Exhibit 1, the Chronoflex embolic filter is attached to a long polyimide tube, which has a lumen that is sized to permit

rotation and translation of the filter element (*i.e.*, the polyimide tube support and the Chronoflex filter mounted thereon) on the guidewire.

63. As shown by Exhibit 2, the inventors disclosed to me that due to the long length of the polyimide tube, which must bend in order to conform to the path followed by the filter element in the arteries, there was friction between the 0.014″ guidewire and the lumen of the polyimide tube, which was 0.145″.

64. Prior to March 5, 1998, the inventors also disclosed to me that there was friction between the exterior of the long polyimide tube and the lumen of the retrieval catheter, which significantly increased the force required to withdraw the embolic filter into the withdrawal catheter, by pulling on the polyimide tube.

65. Prior to March 5, 1998, the inventors informed me that they considered that the stepped 0.013″/0.016″ guidewire configuration described above, which provides a distal stop, would permit the transfer of some of the withdrawal load from the polyimide tube to the guidewire, by retracting the guidewire in a proximal direction to cause the thicker distal guidewire tip portion to abut against the polyimide tube support of the filter element, thus reducing the load on the filter element during withdrawal.

66. Prior to March 5, 1998, the inventors also informed me that they considered that that this stepped guidewire configuration would permit the guidewire to be used to withdraw the expanded filter into a retrieval catheter, by retracting the thicker distal stop portion of the guidewire to abut the end of the polyimide tube filter support, and by pulling the guide wire proximally to retract the filter element into a retrieval catheter.

67. The inventors disclosed to me that retracting the guide wire in a proximal direction causes the distal stop to abut against the filter element, when the guidewire is pulled to retract the filter element into a retrieval catheter, and disclosed this advantage to me prior to March 5, 1998.

68. Prior to March 5, 1998, I understood that the prototype NeuroShield Mark 1 filter system described in Exhibit 90, discussed above, incorporated each of the following aspects of the invention:

| **NeuroShield Mark 1 Prototype (Exhibit 90)** |
| --- |
| The filter system is used in the method disclosed in Irish Application No. 97 0789, where a representative filter is shown, *e.g.*, in Fig. 18.<br><br>The balloon filter shown in Exhibit 90 is mounted on a polyimide tube support having an inner diameter of 0.0145", and the filter is disposed for translation on a guide wire proximal of the distal stop. The polyimide tube support prevents the filter from translating distal of the guidewire stop.<br><br>The balloon filter shown in Exhibit 90 has a number of self-expanding Nitinol shape-memory struts supporting the expanded filter sac, which is attached to the Nitinol support.<br><br>The balloon filter is shown in Exhibit 90, in its deployed configuration, as described in Irish Application No. 97 0789, as it would engage a wall of the vessel and filter emboli out of blood flowing through a vessel in which the filter is deployed.<br><br>Treatment devices such as a balloon catheter or a stent balloon catheter are treatment devices which are inserted into a vessel to treat a portion of the vessel, and in the device shown in Exhibit 90, they are advanced over the guidewire to a position proximal of the filter element, as described in Irish Application No. 97 0789.<br><br>The inner lumen of the polyimide tube filter support shown in Exhibit 90, |

> has a diameter of 0.0145″, and the proximal region of the guidewire used with the filter support has an outer diameter of 0.013″. Exhibit 90 thus confirms that rotation or distal translation of the guide wire relative to the filter element does not displace the filter element. As shown in Exhibit 90, a guidewire can be translated through the filter polyimide tube support without displacing the filter element. The guidewire can also be rotated in the filter polyimide tube support without displacing the filter element.
>
> In order to retrieve the filter, a guidewire is retracted to cause the distal stop to abut against the filter element. The prototype filter system includes a wire lock device, which is used to hold the guidewire in place while the retrieval catheter is pushed over the filter, with the distal stop abutting against the filter element.

## III. DILIGENT EFFORTS TO REDUCE THE INVENTION TO PRACTICE

69. From a time prior to March 5, 1998 until the filing of Irish Patent Application No. 98 0267 on April 8, 1998, the inventors and other members of MedNova were engaged in continuous, diligent efforts to produce and test a practically useful embodiment of their embolic filter inventions defined by Count 1 and Count 2. I may not have been aware of all of the details by all of the inventors and all of the other members of MedNova, but I can confirm that the documents referred to herein are accurate.

70. During the period from late February 1998 until April 8, 1998, the inventors and other MedNova employees working at their direction were intensely involved in preparing for tests of the embolic filter protection system and methods in New York, which were conducted at Montefiore Hospital in the Bronx on March 14, 1998 and again on April 5, 1998.

71. Their preparation for these tests in New York commenced in January 1998, when Chas Taylor contacted Dr. Takao Ohki to arrange for the use of his

laboratory, and also arranged for Dr. Gary Roubin to conduct the test procedures.

72. I was familiar with the preparation of the prototype devices which were tested by Dr. Roubin in New York on March 14, 1998, and April 5, 1998, and with the modifications of the embolic filter which were made to prepare for the April 5, 1998 tests.

73. The March 14, 1998 tests used the "Mark 1" prototype NeuroShield filter device and system, substantially as shown in Exhibit 90.

74. The "NeuroShield" device which Dr. Roubin tested on March 14, 1998 utilized a stepped guidewire having a distal stop. The distal end of the guidewire had a diameter (i.e., 0.016″) that was greater than the inner diameter of the polyimide tube filter support (i.e., 0.0145″), and provided a stop which prevented distal translation of the filter element beyond the guidewire distal stop. The region of the guidewire proximal to the distal stop had a diameter (i.e., 0.013″) that was smaller than the lumen of the polyimide tube supporting the filter. It was therefore possible to rotate and translate the guidewire relative to the filter and its polyimide support.

75. In the "NeuroShield" device which Dr. Roubin tested on March 14, 1998, the balloon filter element had a filter sac attached to a Nitinol framework having a number of self-expanding struts, and the Nitinol framework was attached to a thin polyimide filter support.

76. In the "NeuroShield" device, which Dr. Roubin tested on March 14, 1998, the stepped guidewire was backloaded through the polyimide tube filter support. The distal end of the stepped guidewire would not pass through the polyimide tube filter support, and provided a distal stop on the

guidewire. The filter element was thus disposed for translation on the guidewire proximal of the distal stop.

77. The prototype embolic filter that Dr. Roubin used in the March 14, 1998 tests, including a filter sac supported by self-expanding Nitinol struts, the polyimide tube filter support, and the stepped guidewire, is accurately shown in Exhibit 90.

78. The balloon filter structure of the filter that was used in the March 14, 1998 tests is also schematically shown in Exhibit 65:

79. The expanded filter model used in the March 14, 1998 tests is shown disposed on a mandrel in Exhibit 90. In order to transluminally insert the filter into the vessel, it was necessary to compress the filter using a loading device, and to insert the compressed filter and guidewire into a delivery catheter.

80. The results of the March 14, 1998 tests are described in Paul Gilson's March 18, 1998 memorandum, attached as Exhibit 37, which I received and understood on or about March 18, 1998.

81. After the March 14, 1998 test, the inventors designed a version of the "NeuroShield" embolic filter which provided a filter element intended to provide better rotation and translation movement of the guidewire.

82. On or about March 24, 1998, Paul Gilson disclosed to me the version of the "NeuroShield" embolic filter design that is described Exhibit 60, page 3.

83. On March 24, 1998, I understood that the inventors' changes to prepare the modified "NeuroShield" embolic filter included mounting the filter on a short polyimide tube support to which the Nitinol filter support was bonded. This configuration allowed the filter assembly to move between

pre-determined stops on the guide wire, and thus the wire was free to torque and to have limited movement longitudinally (Exhibit 60, page 3).

84. During the period from March 14, 1998 until April 4, 1998, the inventors and others at MedNova worked intensively and continuously to produce a modified filter design to be used in the tests conducted by Dr. Roubin on April 5, 1998. I am familiar with their efforts during this period, and am familiar with the design of the modified filter that was used in the April 5, 1998 tests. It was a major undertaking to modify the filter element, and to produce additional prototype devices, for the second test of the filter system, within three weeks.

85. On April 5, 1998, Dr. Roubin tested the modified "NeuroShield" embolic filter at Montefiore Hospital in the Bronx, New York, USA. (Exhibits 79, 81).

86. Paul Gilson and Chas Taylor attended the April 5, 1998 test.

87. The "NeuroShield" device tested on April 5, 1998 utilized a stepped (0.013″/0.016″) guidewire having an improved distal stop.

88. In the revised "NeuroShield" device, the stepped guidewire was preloaded through a balloon filter element having a filter sac which was affixed to a Nitinol support having a number of self-expanding struts.

89. In the revised "NeuroShield" device, the Nitinol framework was attached to a short (about 40 mm) polyimide tube support disposed proximal of the distal stop between the distal stop and a proximal stop, as shown in Exhibit 60, page 3, and Exhibits 81 and 88). Because the short polyimide tube had a lumen with an inner diameter smaller than the diameter of the distal stop of the guidewire, the distal end of the guidewire would not pass through the polyimide tube and provided a distal stop. The filter element was disposed

for translation and rotation on the stepped guidewire proximal of the distal stop.

90. The short polyimide tube (about 40 mm) floated on the guidewire between the distal stop and the proximal stop. The filter element was thus capable of rotation and distal translation with respect to the guidewire in a manner equivalent to the earlier version of the device.

91. The modified NeuroShield filter and guidewire which Dr. Roubin tested on April 5, 1998, are accurately described in the drawing prepared by David Vale on or before April 8, 1998, contained in from Exhibit 81.

92. Based on the two tests conducted by Dr. Roubin, the inventors and others at MedNova working at their direction continued to modify, improve, and perfect the filter system from April 5, 1998 until April 8, 1998, when Irish Application No. 98 0267 was filed.

93. Their continuous efforts during the period from prior to March 5, 1998 until April 8, 1998, were directed at improving the parts of the filter element, as well as components such as the delivery catheter used to transluminally insert the guidewire and filter element into a vessel, and to perform other steps of the methods.

94. These efforts are described in numerous documents, including detailed filter development Project Team Meeting Reviews, summarizing the activities of each team member directed toward an actual reduction to practice in the preceding and following week. The Project Team Meeting Reviews are documents that were regularly prepared in the course of business by Eamon Brady and/or Chas Taylor, shortly after the team's meetings on the dates indicated in the reports. The reports were regularly distributed to the team members working on the embolic filter project, as

well as to John O'Shaughnessy and to me, and are maintained by Eamon Brady in MedNova's files relating to the project. They accurately describe MedNova's efforts to produce and improve the embolic filter system during the period from late February 1998 to April 8, 1998.

95. To the extent that I may not have personal knowledge of each of the documents referred to herein, on information and belief, I believe that the orders, invoices, specifications, reports, emails, memoranda and other documents attached as exhibits are true copies of contemporaneous documents made and kept by MedNova in the regular course of business, and that they accurately reflect the activities of the inventors and other MedNova employees on the dates indicated in the documents.

96. During the period from February 1998 until April 8, 1998, the entire focus of MedNova's effort was to produce and test a prototype embolic protection filter, which could be shown to work effectively in removing emboli during carotid artery angioplasty and stenting procedures. The members of the embolic protection filter team worked closely and in coordination to design and make the various components of the systems used by Dr. Roubin to carry out the tests.

97. The Project Team Meeting Reviews and other documents demonstrate that the inventors and other engineers were working intensely and continuously to produce a filter and system that would be shown to be practically useful in the tests conducted by Dr. Roubin, during the period from just prior to March 5, 1998, until April 8, 1998. These Project Team Meeting Reviews and other documents are attached as the following exhibits:

| | |
|---|---|
| February 25, 1998: | Exhibit 8 |
| March 5, 1998: | Exhibit 22 |
| March 11, 1998: | Exhibit 33 |

| | |
|---|---|
| March 18, 1998: | Exhibit 48 |
| March 24, 1998: | Exhibit 38 |
| April 1, 1998: | Exhibit 74 |
| April 6, 1998: | Exhibit 83 |

98. During the period from February 1998 until April 8, 1998, Paul Gilson arranged in February 1998 for Dr. Roubin to conduct the tests; coordinated the tests in New York on March 14, 1998 and April 5, 1998; traveled to New York to attend these tests; evaluated the results of the tests; modified and improved the filter to improve movement of the guidewire relative to the filter; and worked with Dr. Roubin in evaluating the design changes proposed by the inventors.

99. During the period from February 1998 until April 8, 1998, Susan Eighan, who was a Manufacturing Engineer, worked to make final packs for the tests conducted by Dr. Roubin (Exh. 22, 33), as well as working on the core removal process for making the filter balloon sacs (Exh. 33), making and improving Nitinol supports (Exh. 33, 77, 83), building filter samples (Exh. 48); and manufacturing the filter assembly (Exh. 38, page 2).

100. During the period from February 1998 until April 8, 1998, Steven Horan, who was a Research and Development Engineer, worked principally on the balloon filter sac, including narrowing the balloon wall thickness distribution, updating the dip and core assembly procedures used to make the balloons, and conducting tests of the balloons (Exh. 8, 22); building 36 balloons for the tests conducted by Dr. Roubin (Exh. 22, 33); analyzing balloon data and evaluating balloon strengths, ordering cores for making the balloons, and dipping balloons for UV trials (Exh. 33, 48); prototyping alternative balloons for the April 5, 1998 trials in New York (Exh. 38, page 1), including tapered filter or stepped filter or grooved filter designs to

improve filter performance in undersized vessels (Exh. 74); making and testing about 35 prototype balloons for the April 5, 1998 trials (Exh. 77); and evaluating and testing a series of filter geometries and sizes (Exh. 83).

101. During the period from February 1998 until April 8, 1998, Padraig Maher, who was a Research and Development Engineer, tested Nitinol supports, provided samples of the Nitinol supports to a laser machine company, and tested the loading force required to load the filter element into a delivery catheter and tested the maneuverability of the delivery catheter (Exh. 8, 22, 33); defined a balloon wrap method (Exh. 22, 33); worked on a suggestion from Chas Taylor to increase the number of distal holes in the balloon filter (Exh. 38, page 2); worked to increase the size of the proximal filter holes (Exh. 83); and built "olives" to improve the transition from the delivery catheter to the filter element (Exh. 74, 77, 83).

102. During the period from February 1998 until April 8, 1998, Keith Ryan, a technician, worked with David Vale on developing the delivery catheter pod used to transluminally insert the filter and guidewire past the plaque, and tested pod tensile strengths (Exh. 8); worked on the rig used to test the PTFE pod attachment (Exh. 22); built 10 loading mechanisms for use in the trials, which were used to load the filter element into the delivery catheter (Exh. 33); tested additional loading mechanisms (Exh. 77, 83); and worked on the wall thickness and diameter of the Teflon pod of the delivery catheter (Exh 74, 77); and modified the loading mechanism transition of the delivery catheter (Exh. 77, 83).

103. During the period from February 1998 until April 8, 1998, David Vale, who was Senior Research and Development Engineer, worked on the retrieval catheter specifications (Exh. 22, 33); worked on the delivery catheter (Exh.

38, page 2); modified the filter element design, and worked on the stops for the filter, as well as materials and processes for the stops on the guidewire (Exh. 74, 77); designed, built and evaluated a filter design with floating distal bonds (Exh. 83); and worked on improving the smoothness of guidewire transitions and improving guidewire stiffness (Exh. 83, page 2).

104. The activities of the inventors and other MedNova employees, in the period from February 25, 1998 until April 8, 1998 are described in more detail in the Project Team Meeting Reviews as follows.

105. Exhibit 8 is a Project Team Meeting Review of the MedNova research team working on development of the embolic filter invention, which took place on February 25, 1998.

106. The attendees at the February 25, 1998 meeting were as follows: Shivaun O'Rourke ("SOR"); Steven Horan ("SH"); Padraig Maher ("PM"); Mary Gallagher ("MG"); Keith Ryan ("KR"); David Vale ("DV"); Jon Hager ("JH"); Susan Eighan ("SE"); and Eamon Brady ("EB"). Copies of the project team meeting review were sent to the project file, maintained by Eamon Brady and were sent to me, Chas Taylor ("CT"), and Paul Gilson ("PG").

107. The responsibilities of MedNova's research team working on the embolic filter development project in February and March 1998 are correctly stated in Exhibit 8.

108. Keith Ryan was generally responsible for PTFE shrink development work, which was necessary to make the delivery catheter used to transluminally insert the filter element into a vessel.

109. Shivaun O'Rourke was generally responsible for activities in support of test development and evaluation of prototype devices, including embolic filter prototypes.

110. Susan Eighan was generally responsible for catheter manufacturing line setup, and for Nitinol forming and balloon process bond development used in producing the embolic filter element assemblies.

111. Padraig Maher was generally responsible for core punching, core assembly and specifications for the cores used to produce the filter sac used in the embolic filter element.

112. Jon Hager was generally responsible for vendor approval, receiving goods system, and documentation. He was also responsible for DMR (device master record) development, which defines how the device is built.

113. David Vale was generally responsible for producing the retrieval catheter used to retrieve the filter element from the artery after performance of carotid artery angioplasty procedures, for development of the loading mechanism for compressing the expanded balloon filter and loading it into the delivery catheter, and for packaging.

114. Steven Horan was generally responsible for filter sac ("balloon") development.

115. Chas Taylor was generally responsible for labeling and instructions.

116. In the week prior to February 25, 1998, Keith Ryan tested pod tensile strengths, for the pod used to deliver the catheter, and Shivaun O'Rourke updated the pod shrink validation protocol.

117. In the week prior to February 25, 1998, Susan Eighan started building delivery catheters for sterilization and completed building assemblies to the point of balloon bond.

118. In the week prior to February 25, 1998, Padraig Maher tested the Nitinol framework used to expand the filter element, and sent samples to the laser company that laser machined the Nitinol frame.

119. In the week prior to February 25, 1998, Jon Hager inspected dipped balloons used as the filter sac in the self-expanding filter.

120. In the week prior to February 25, 1998, David Vale worked in defining the pod shrink process used in producing the filter delivery catheter, and initiated the construction of the packaging.

121. In the week prior to February 25, 1998, Steven Horan analysed Taguchi test results, which related to optimizing the process for making the filter sacs, and updated the dip and core assembly procedures used to produce the filter sac balloons. Steven Horan on February 25, 1998, prepared document no. MP97 009, revision 5 (Exhibit 9) which describes the method used to assemble the soluble core assembly that is used to make the Chronoflex balloon.

122. On February 25, 1998, David Vale prepared document no. TP97022, (Exhibit 10), which describes the method for determining and quantifying the integrity of the retrieval catheter tip under a compressive load. A retrieval catheter is used to collapse the self-expanding embolic filter after the procedure is completed.

123. Invoices and other records made and maintained by MedNova in the regular course of business show that in the week following February 25, 1998, MedNova's vendors supplied materials that were used in preparing prototype filter systems, and MedNova ordered additional supplies related to producing the prototype systems. These documents demonstrate that MedNova was engaged in a continuous effort to obtain supplies used to

produce and test prototype embolic filter devices used in the methods according to Counts 1 and 2 during this period.

124. On February 26, 1998, MedNova received a shipment of Monel wire from Fairbanks Wire Co. (Exhibit 11), which was required to produce the loading funnel and delivery catheter pod.

125. On February 26, 1998, Boston Scientific shipped vials of Contour™ particles to Chas Taylor (Exhibit 97), which were required to produce test embolic material capture. Exhibit 101 is a photograph of five of the bottles of the Countour™ particles received from Boston Scientific.

126. On February 26, 1998, Payne Plastics shipped machined Perspex rod to MedNova (Exhibit 12), which was required to produce the loading funnel. This shipment was received on March 4, 1998.

127. On February 27, 1998, Dawnlough, Ltd. shipped Perspex rod to MedNova (Exhibit 13), which was received on March 6, 1998. This rod was required to produce the loading funnel.

128. On February 27, 1998, Euroflex shipped laser cut parts from Nitinol slit tubing, according to drawing CE 97 003, Rev. 04 (Exhibit 14). These parts were required to produce Nitinol supports for the embolic filter element.

129. On February 27, 1998, MedNova ordered closed coil stainless steel spring according to specification CD 97 002 from Ashfield Springs (Exhibit 15). These springs were required to produce the delivery catheter, and were shipped March 18, 1998 (Exhibit 20).

130. On February 27, 1998, MedNova issued a purchase order to Adam Spence for a spline press tool (Exhibit 16), which was used to produce the retrieval catheter distal tip.

131. On February 28, 1998, Dawnlough, Ltd. shipped Nitinol formers to MedNova (Exhibit 96), which were required to produce the self-expanding Nitinol struts for the embolic filter element. The Nitinol formers were received on March 11, 1998.

132. On March 2, 1998, Medical Profiles Inc. shipped hemostasis Y-connectors to MedNova (Exhibit 18), which were required to produce the delivery catheters.

133. On March 3, 1998, MedNova ordered from National Heat Treatment Centre, UCD, the annealing of Monel 400 wire (Exhibit 21). This wire was required to produce the delivery catheter, pod and loading funnel. The heat-treated wire was shipped on March 30, 1998, and was received on March 31, 1998. (Exhibit 17).

134. Exhibit 22 is a Project Team Meeting Review of the MedNova research team working on development of the embolic filter invention, which took place on March 5, 1998.

135. The attendees at the March 5, 1998 meeting were as follows: Shivaun O'Rourke ("SOR"); Steven Horan ("SH"); Padraig Maher ("PM"); Keith Ryan ("KR"); David Vale ("DV"); Jon Hager ("JH"); Susan Eighan ("SE"); and Eamon Brady ("EB"). Copies of the project team meeting review were sent to the project file, me ("MC"), Chas Taylor ("CT"), and Paul Gilson ("PG").

136. The general responsibilities of MedNova's research team members working on the embolic filter development project in March 1998 are correctly stated in Exhibit 22.

137. In the week prior to March 5, 1998, Keith Ryan wrote a pouch seal procedure used to seal the product into a packaging pouch.

138. In the week prior to March 5, 1998, Shivaun O'Rourke drafted a pouch seal protocol, and prepared a validation protocol for the Touhy Borst connector used in the delivery catheter.

139. In the week prior to March 5, 1998, Susan Eighan worked on building the filter element to the balloon bond and the delivery catheter to the point of pod attachment.

140. In the week prior to March 5, 1998, Padraig Maher conducted short length and full length loading force measurement testing on the filter and loading funnel, which related to measuring the ease of filter loading. He also conducted full length loading force testing on the filter system, which related to the forces experienced by the end user.

141. In the week prior to March 5, 1998, Steven Horan worked on the expandable filter sac balloons, narrowing the balloon wall thickness distribution, and completed a trial with vacuum for removal of bubbles, which was necessary to improve process control.

142. On or about March 2, 1998, a protocol was prepared for a maneuverability test fixture, which was a template which simulates the path likely to be taken by a guide catheter in reaching the site of a carotid intervention. (Exhibit 23). This model was designed to test the delivery catheter used to transluminally insert the filter element into a vessel, and represented a tortuous path of insertion. The model is used to estimate the force required to insert or withdraw catheters in vessels. On or about March 2, 1998, a test protocol TP97 017 was drafted describing this procedure (Exhibit 24). The February 25, 1998, Project Team Meeting Review indicates that on of the next week's key goals for Mr. Maher was full length loading force testing and maneuverability test rig design. (Exhibit 8).

143. Shivaun O'Rourke drafted a protocol for calibration of flow meters used to measure the flow rate in a test rig simulating the flow of blood in a simulated carotid artery (Exhibit 25, dated March 2, 1998). This device was used to test embolic capture ability, and is illustrated in a drawing prepared by Shivaun O'Rourke or Jon Hager on March 3, 1998 (Exhibit 26).

144. Keith Ryan prepared a screening validation procedure for the process used to shrink PTFE tubing onto a copper mandrel for preparing the delivery pod and loading funnel, and a test method for measuring PTFE integrity and its bond strength to the loading funnel (Exhibit 19, dated March 4, 1998).

145. Padraig Maher prepared a drawing of a test rig used to test the force required to retrieve the embolic protection filter into the pod of the retrieval catheter (Exhibit 26, dated March 4, 1998).

146. The March 5, 1998 Project Team Meeting Review (Exhibit 22) confirms that at this time we were preparing for the tests of the embolic filter protection system in New York.

147. Exhibit 22 indicates that a key goal for Steven Horan in the next week was building 10 balloons for filters to be used in the tests, and that a key goal for Susan Eighan was to build 10 final packs for the trials.

148. Exhibit 22 describes the next week's key goals for team members, in the week following March 5, 1998, as follows.

149. Keith Ryan's key goals included defining a pouch seal process window, which related to packaging.

150. Shivaun O'Rourke's key goals included approving a pod shrink protocol, which related to testing the manufacturing outputs from the pod shrink test protocol, and approving the pouch seal protocol.

151. Susan Eighan's key goals included building 10 final packs for the tests of the use of the embolic protection system evaluating the filter element to the balloon bond post sterilization, and finalizing the core removal process, which was used in making the balloon filter membrane sacs.

152. Padraig Maher's key goals included fatigue and tensile tests of the Nitinol frame, and defining a sac wrap method for loading.

153. David Vale's key goals included updating the retrieval catheter specification, ordering retrieval catheter bench test parts, and building sterility pieces used for post sterile testing of retrieval catheter.

154. Steven Horan's key goals included building 10 balloons for the Ohki trials, and building balloons for post sterility testing.

155. On March 6, 1998, Shivaun O'Rourke reported on the status of process screening validations for components of the embolic filter protection device system, including Nitinol forming and balloon bonding screening for the filter; delivery catheter pod shrinkage screening, and preparation of the delivery catheter loading pod by shrinkage of PTFE onto Monel wire; and the validation of the Touhy Borst adapter (Exhibit 39).

156. David Vale prepared a drawing (Exhibit 28, dated March 6, 1998) with specifications for the retrieval catheter assembly (SA97 006 Rev. 2) used to retrieve the filter element from a vessel after treatment of the vessel. A copy of this specification was sent to Adam Spence with an order for to retrieval catheters made according to the revised specification on March 6, 1998. (Exhibit 29).

157. Keith Ryan prepared a drawing (Exhibit 30, dated March 9, 1998) and specification (SA98 006 Rev 01) for the delivery catheter used for transluminally inserting the filter element into a vessel. This drawing

illustrates the Touhy Borst connector, catheter spring shaft having a shrunk PTFE cover, and distal PTFE pod that is used to hold the compressed balloon filter assembly during transluminal insertion.

158. Keith Ryan prepared a specification (SA98 005 revision 01) for the loading mechanism subassembly, which is used to compress and load the balloon filter into the delivery catheter. (Exhibit 34, dated March 10, 1998).

159. On March 11, 1998, Chas Taylor sent a facsimile to Paul Gilson and Dr. Gary Roubin, making final arrangements for meeting in New York at Montefiore Hospital to conduct tests of the embolic filter system. (Exhibit 31).

160. Steven Horan prepared a drawing (Exhibit 32, dated March 9, 1998) and specification (CC98 001 Rev. 01) of the soluble core used to make the balloon used as a filter sac in the embolic filter element.

161. Exhibit 33 is a Project Team Meeting Review of the MedNova research team working on development of the embolic filter invention, which took place on March 11, 1998.

162. The attendees at the March 11, 1998 meeting were as follows: Shivaun O'Rourke ("SOR"); Steven Horan ("SH"); Padraig Maher ("PM"); Keith Ryan ("KR"); David Vale ("DV"); Jon Hager ("JH"); Susan Eighan ("SE"); myself ("MC"); Paul Gilson ("PG") and Eamon Brady ("EB"). Copies of the project team meeting review were sent to the project file maintained by Eamon Brady.

163. The responsibilities of MedNova's research team working on the embolic filter development project in March 1998 are correctly stated in Exhibit 33.

164. In the week prior to March 11, 1998, Keith Ryan built 10 loading mechanisms for the trials in New York.

165. In the week prior to March 11, 1998, Shivaun O'Rourke approved the pouch seal protocol, relating to packaging.

166. In the week prior to March 11, 1998, Susan Eighan built 10 final packs for the trials in New York, and completed the delivery catheter sterility/bio build.

167. In the week prior to March 11, 1998, Padraig Maher fatigued tested Nitinol struts used in the balloon filters, and analyzed loading force data relating to filter assembly loading.

168. In the week prior to March 11, 1998, David Vale updated the retrieval catheter specification (Exhibit 28), ordered retrieval catheter bench test parts (Exhibit 33), and had built retrieval catheters for post sterility testing.

169. In the week prior to March 11, 1998, Steven Horan built 36 balloons for the tests in New York.

170. Exhibit 33 describes the next week's key goals for team members for the week following March 11, 1998, as follows.

171. Keith Ryan's key goals for the week included defining a pouch seal process window, and pod screening of the overlap joint, which related to the delivery catheter.

172. Shivaun O'Rourke's key goals for the week included approving the pod shrink protocol and updating the pod shrink validation, both of which related to the delivery catheter.

173. Susan Eighan's key goals for the week included evaluating the filter element to the balloon bond post sterilization, resolving Teflon shrink process issues, finalizing the core removal process used to produce the filter balloon sacs, and putting process controls in place to correct a Nitinol cracking issue.

174. Padraig Maher's key goals included writing up Nitinol test results, and evaluating deployment and retrieval force encountered in inserting and removing the embolic filter.

175. David Vale's key goals included completing pod engineering studies, which related to the delivery catheter.

176. Steven Horan's key goals related to development of the balloon filter sac and related to process development of the filter sac, analyzing balloon data, evaluating balloon strengths, dipping balloons for UV adhesive bonding trials, and ordering cores for making the balloon filters.

177. On March 12, 1998, MedNova ordered Y-connectors from Qosina (Exhibit 57), which were required for the delivery catheters. The purchase order was received by Qosina March 13, 1998 (Exhibit 35). These parts were shipped on March 16, 1998, and were received on March 20, 1998 (Exhibit 36).

178. On March 14, 1998, Dr. Gary Roubin performed a test of MedNova embolic protection systems. This test was attended by Paul Gilson and Chas Taylor. Exhibit 37 is a report of the *in vitro* plaque filtration test prepared by Paul Gilson.

179. In the week following the March 14, 1998 trial in New York, Paul Gilson returned to Ireland and the MedNova research team worked to modify the embolic filter protection system. These proposed changes were discussed at a meeting on March 23, 1998, attended by Paul Gilson, Padraig Maher; Steven Horan, David Vale, Susan Eighan, me, Chas Taylor and Eamon Brady.

180. Eamon Brady prepared a summary of the Design Review Meeting and distributed the Design Review Minutes to the participants on March 24, 1998 (Exhibit 38).

181. Among other improvements to the embolic protection filter system, we discussed modifying the balloon design to improve the sizing performance of the filter in vessels of smaller size, and improving wire movement. (Exhibit 38).

182. Steven Horan was assigned responsibility for prototyping a series of alternative balloon designs, intended to improve sizing performance in vessels of smaller size. (Exhibit 38)

183. The inventors decided to increase the delivery catheter shaft outer diameter to accommodate the internal pusher for deploying the filter element. (Exhibit 38).

184. The inventors decided to change the filter element by changing the long polyimide tube on which the expandable balloon filter is mounted to a short length of polyimide, which is mounted on the wire but can move on the wire between two stops. (Exhibit 38, page 2). This modification design has the advantage of facilitating wire movement independent of the filter element.

185. Padraig Maher and Susan Eighan were assigned responsibility for preparing prototypes of the modified filter assembly design by April 2, 1998, for evaluation in the Ohki model. (Exhibit 38, page 2).

186. On March 17, 1998, Payne Plastics shipped machined Perspex rod which was required to make the loading funnel. This shipment was received on April 3, 1998. (Exhibit 40).

187. Padraig Maher prepared a specification (SA98 003 revision 02) for preparing coated acrylic core with laser machined holes at each end, for making balloon filter sacs. (Exhibit 41, dated March 18, 1998).

188. On March 18, 1998, MedNova ordered laser machined coated core parts according to Specification SA98 002, revision 2, from Spectralytics, Inc., a laser machining company (Exhibit 42). These parts were received on April 6, 1998. (Exhibit 43).

189. On March 26, 1998, Padraig Maher modified the specification for laser machined core parts, based on Spectralytics' processing capabilities could hold. (Exhibit 44). Padraig Maher prepared specification SA98 003, revision 3, relating to the acrylic core parts for preparing filter sacs, on March 26, 1998 (Exhibit 45).

190. On March 18, 1998, MedNova ordered UV adhesive from Murphy Engineers (Exhibit 46), for use by Susan Eighan in conducting UV bonding studies (Exhibit 33). This material was shipped on April 6, 1998. (Exhibit 47).

191. Exhibit 48 is a Project Team Meeting Review of the MedNova research team working on development of the embolic filter invention, which took place on March 18, 1998.

192. The attendees at the March 18, 1998 meeting were as follows: Shivaun O'Rourke ("SOR"); Steven Horan ("SH"); Padraig Maher ("PM"); Keith Ryan ("KR"); Jon Hager ("JH"); Susan Eighan ("SE"); myself ("MC"); and Eamon Brady ("EB"). Copies of the project team meeting review were sent to the project file, maintained by Eamon Brady; copies were also sent to David Vale ("DV"), and Paul Gilson ("PG").

193. The general responsibilities of MedNova's research team members working on the embolic filter development project in March 1998 are correctly stated in Exhibit 48.

194. In the week prior to March 18, 1998, Keith Ryan improved process control on the PTFE rig, relating to making the delivery catheter.

195. In the week prior to March 18, 1998, Susan Eighan built filter samples.

196. In the week prior to March 18, 1998, Padraig Maher wrote up Nitinol test results.

197. In the week prior to March 18, 1998, Steven Horan analyzed balloon dip data, evaluated balloon strengths, and ordered cores for preparing filter balloon sacs.

198. Exhibit 48 describes the next week's key goals for team members, in the week following March 18, 1998, as follows.

199. Keith Ryan's key goals included defining a pouch seal process window, resolving Monel wire/PTFE issues, which related to the delivery catheter pod and loading funnel, and building a test product.

200. Shivaun O'Rourke's key goals included approving the pod shrink process validation protocol, which related to the delivery catheter pod, and updating the pod shrink validation.

201. Susan Eighan's key goals included resolving Teflon shrink process issues, which related to the delivery catheter, finalizing the core removal process, which related to the filter sac, and UV bonding studies, which related to the filter sac bonding to the polyimide tube.

202. Padraig Maher's key goals included retesting the new loading mechanism design for loading the filter element into the delivery catheter, evaluating

deployment and retrieval force, and defining a balloon wrap method for the balloon filter.

203. Steven Horan's key goals related to development of the balloon filter, and included dipping balloons for UV bonding trials, reducing the balloon wall thickness, and providing test balloons for Susan Eighan for UV bond testing.

204. On March 19, 1998, MedNova ordered close coiled stainless steel springs from Ashfield Springs, for use in making delivery catheters. (Exhibit 49). These springs were ordered by Padraig Maher. (Exhibit 50). These springs were received on March 31, 1998. (Exhibit 87)

205. On March 19, 1998, Keith Ryan described a procedure for bonding subassemblies to make the filter loading device. (Exhibit 52).

206. From March 18, 1998, to March 20, 1998, Steven Horan prepared a specification (CC97 007, revision 03), describing the 6 mm soluble core used to make filter balloon sacs. (Exhibit 53).

207. From March 18, 1998, to March 20, 1998, Steven Horan prepared a specification (CC97 010, revision 03), describing the 5 mm soluble core used to make filter balloon sacs. (Exhibit 54).

208. On March 19, 1998, Jon Hager prepared a specification (SA98 008 revision 01), describing the filter element, including a polyimide tube and a balloon filter mounted on a Nitinol framework. (Exhibit 55).

209. On March 23, 1998, MedNova ordered heat shrink PTFE tubing, according to specification CB97 002, for use in making delivery catheters. (Exhibit 56).

210. On March 23, 1998, MedNova requested a quote for polyimide tubing from MicroLumen, for use in making filter elements. (Exhibit 57).

211. On March 24, 1998, David Vale prepared drawings of a new modification of the filter element, having a filter sac supported on self-expanding Nitinol struts, where the filter is mounted on a short section of polyimide tubing. (Exhibit 58). As shown in Exhibit 58, the short section of polyimide tubing has an inner lumen diameter of 0.0145″ and an outer diameter of 0.0185″, and is mounted on a dual diameter guidewire, with a proximal section having a diameter of 0.013″, between a proximal stopper and the distal stopper which permit both distal translation of the guide wire relative to the filter element, and rotation of the guide wire relative to the filter element, which do not displace the filter element. The distal end of the dual diameter guidewire has a diameter of 0.016″.

212. On or about March 24, 1998 the inventors disclosed the filter design described in Exhibit 58 to me, and indicated that they considered that this design would provide excellent wire movement, in that the filter position would not be so much affected by jerky movements when exchanging angioplasty or stent devices over the guidewire. They also disclosed to me that this design would eliminate frictional problems with the long polyimide tube support of the filter element. The considered that a larger diameter spring would be required for the delivery catheter shaft. (Exhibit 59). Susan Eighan was to make new Nitinol formers for the redesigned filter element. (Exhibit 58).

213. In a facsimile dated March 24, 1998, Paul Gilson explained to Dr. Gary Roubin proposed changes to the filter element, which included shortening the polyimide tube of the filter element on which the filter is bonded. Paul Gilson explained that the filter assembly is free to move between pre-determined stops on the guide wire, and thus the wire will be free to torque

and to have movement longitudinally. Paul Gilson informed Dr. Roubin that MedNova would be ready by April 3rd or 4th to evaluate these design changes. (Exhibit 60).

214. On March 24, 1998, MedNova ordered close coiled stainless steel tensioned springs from Ashfield Springs, to make a "pusher" to deploy the filter element, as discussed in Exhibits 58 and 59. (Exhibit 60). These springs were received on March 31, 1998. (Exhibit 62).

215. On March 24, 1998, at the request of Paul Gilson, MedNova received from Tom Kleist of Lake Region Manufacturing a drawing of the custom .013″/.016″ guidewire which they had previously supplied to MedNova. (Exhibit 63).

216. On March 25, 1998, MicroLumen shipped three sizes of polyimide tubing for use in making prototype filter elements according to the modified design. (Exhibit 64).

217. On March 26, 1998, David Vale sent to Paul Gilson an email containing an attachment with three drawings, including a filter element having an internal Nitinol support, a filter sac mounted on the Nitinol support having inlet and outlet holes, a platinum marker band, and a polyimide shaft. The drawings also described a filter delivery catheter, for transluminally inserting the filter element into a vessel, and a retrieval catheter for removing the filter element from the vessel after completing the procedure. (Exhibit 65).

218. On March 26, 1998, Eamon Brady prepared a drawing of an embolic filter protection device, in preparation for filing Irish Application 98 267. (Exhibit 66).

219. On March 26, 1998, MedNova ordered laser machined coated core parts from SpectraLytics, for use in forming filter sac balloons. (Exhibit 67). These parts were shipped on April 7, 1998, and were received on April 14, 1998. (Exhibit 68).

220. On March 27, 1998, Jon Hager inspected retrieval catheters produced by Adam Spence Limited. (Exhibit 71). On March 30, 1998, Jon Hager prepared a non-conformance report, concluding that the retrieval catheters were too short. (Exhibit 72).

221. On March 31, 1998, Dawnlough, Ltd. shipped to MedNova pin punch assemblies and units used in the production of filter membranes. (Exhibit 73).

222. On April 1, 1998, Eamon Brady prepared a list of design activities to implement the modified embolic filter. (Exhibit 74). These changes included shortening the polyimide tube support for the balloon filter. In order to make this change, it was necessary to prepare a detailed guidewire specification and specify in detail a proximal stop. Additional design changes to the balloon filter discussed in Exhibit 74 include the use of a tapered filter or stepped filter or grooved filter sac to improve filter performance in undersized vessels. Exhibit 74 also discusses contemplated changes to the delivery catheter, including modifying the attachment of the Touhy Borst connector, increasing the wall thickness of the Teflon shrink cover for the catheter shaft, and modifying the catheter design to permit a force to be applied to the proximal end of the floating filter.

223. On April 1, 1998, David Vale prepared a drawing of the stepped guidewire, having a distal soft tip diameter (E) of 0.018″, and an uncoated proximal diameter (G) of 0.013″. (Exhibit 75).

224. On April 2, 1998, Eamon Brady described the status of the preparation, for the April test in New York using the Ohki model. Following the March 14, 1998 tests in New York, approximately 35 balloons had been dipped and punched. (Exhibit 77).

225. As described in Exhibit 77, on April 2, 1998, Steven Horan selected a batch of balloons, and carried out a tensile evaluation to prepare the filters for use in the April test.

226. As described in Exhibit 77, on April 2, 1998, Susan Eighan formed Nitinol frame support pieces for the modified filter element.

227. As described in Exhibit 77, on April 2, 1998, David Vale and Keith Ryan worked to build delivery catheters with modified loading mechanisms for the modified filter.

228. As described in Exhibit 77, on April 2, 1998, David Vale also evaluated adhesives to bond a stopper to the guide wire.

229. As stated in Exhibit 77, MedNova employees worked to have the modified embolic filter systems built by the evening of April 2, 1998, and to evaluate the new design in a test rig on April 3, 1998, prior to Paul Gilson's departure to New York for the trial.

230. On April 2, 1998, David Vale contacted Lake Region Manufacturing, in a facsimile describing the detailed specification for the stepped guidewire (Exhibit 75), and requested information concerning the guidewire material and tensile strength, the coating material, the expected strengths of the soft tip and bond, and clearances on the dimensions shown in the drawing. (Exhibit 78).

231. On April 5, 1998, Dr. Gary Roubin conducted tests of the modified design in New York, at Montefiore Hospital. (Exhibit 79), attended by Paul

Gilson. In these tests, there were improvements in wire movement in interface, as well as handling of the filter during both preparation and use.

232. The filter of the three NeuroShield embolic filters used in the April 5, 1998 tests in New York are described in a memo from David Vale to Paul Gilson, Eamon Brady, Padraig Maher, Susan Eighan, Keith Ryan, and the design history file. (Exhibit 81). I was familiar with the design of the filter used in the April 5, 1998, tests at that time.

233. Exhibit 81 describes the prototype filter that was assembled on April 3, 1998, and tested in New York on April 5, 1998, as having a guide wire having a distal stop ("stopper") mounted on the stepped guidewire having a 0.013″ proximal diameter and a 0.016″ distal tip diameter; a self-expanding filter element mounted on the guidewire proximal of the distal stop, and disposed for translation and rotation on the guide wire between the distal stop and the proximal stop; the filter element having a filter sac of modified geometry mounted on a short polyimide tube, shown in its expanded configuration. The balloon filter was attached to a Nitinol framework having self-expanding struts.

234. The structure of the filter element used in the April 5, 1998, trials in New York is further described in Exhibit 82, which is a page from the laboratory notebook of Padraig Maher made on April 8, 1998.

235. Exhibit 82 confirms that in the modified filter element, the 3 m long polyimide tube support was shortened to be about 40 mm long, which was mounted between two stops (*i.e.*, a proximal stop and a distal stop) on the guide wire. The filter mounted on the polyimide tube floated between the two stops, and was capable of rotation and distal translation on the guidewire. The filter had a membrane sac, affixed to a Nitinol support that

was affixed to the polyimide tube. When the guidewire was withdrawn in a proximal direction, the distal stopper at the distal end of the guidewire would abut against the polyimide tube support of the filter.

236. In an email dated April 6, 1998, Eamon Brady described the results of the second trial on April 5, 1998. (Exhibit 83). This email was sent to Steven Horan, Padraig Maher, Keith Ryan, David Vale, Susan Eighan, Paul Gilson, and me.

237. Exhibit 83 discusses further design changes to the embolic filter system, including improvement of the UV bonding process, used to bond the filter to the polyimide tube; reducing the frictional coefficient between the polyimide tube support of the balloon filter and the guidewire, to provide free movement between the polyimide and the wire; evaluating a series of filter geometries and selecting the best balloon geometry; testing a polyimide support for the balloon filter; making the proximal filter sac holes larger; and improving the guidewire stiffness.

238. On April 6, 1998, MedNova ordered additional Nitinol tubing from Euroflex, to prepare Nitinol supports for filter elements. (Exhibit 84). The modified design for the Nitinol struts was discussed in a facsimile from David Vale to Euroflex dated April 6, 1998. (Exhibit 84).

239. On April 6, 1998, Jon Hager conducted a quality inspection of retrieval catheters produced by Adam Spence. (Exhibit 85).

240. On April 7, 1998, David Vale requested a quotation from Microgroup for an order of stainless steel cut tube parts, for use as proximal and distal stoppers to be mounted on the guidewire for the floating filter design. (Exhibit 86).

241. Throughout the period from just prior to March 5, 1998, until April 8, 1998, Paul Gilson, Padraig Maher, David Vale, Chas Taylor, Eamon Brady, myself, Susan Eighan, Keith Ryan, Jon Hager, Shivaun O'Rourke, and Steven Horan were engaged in continuous efforts to refine and perfect different elements and features of the prototype embolic protection filter systems and devices discussed herein, in order to demonstrate their practical utility in the methods recited in Count 1 and Count 2.

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 20th December 2005

Mairsil Claffey